IT-supported clinical pathways - highly effective tools for clinical studies

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Clinimetry (clinical studies) – a balance

Chirurg (1998) 69: 325-332



Klinimetrie (klinische Studien) – Bilanz

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problems: sufficient patients

data aquisition

patient's consent

costs

Surgical problem: postoperative wound infections

- delays recovery and often increases length of stay
- causes lasting sequelae
- prevention or reduction is relevant to quality patient care

International Federation of Infection Control

idea/hypothesis: may antiseptic coating of surgical

normal abdominal closure:

sutures reduce wound infections?

PDS® (Polydioxanone) – suture without antibiotic properties

VS.

antiseptic coated suture

Triclosan

5-chloro-2-(2,4-dichlorophenoxy)phenol

Method of action:

- inhibiting fatty acid synthesis.
- binds to bacterial enoyl-acyl carrier protein reductase enzyme (ENR), encoded by the gene Fabl
- formation of a stable ternary complex of ENR-NAD+-triclosan
- unable to participate in fatty acid synthesis
- humans do not have an ENR enzyme -> are not affected

Triclosan

5-chloro-2-(2,4-dichlorophenoxy)phenol

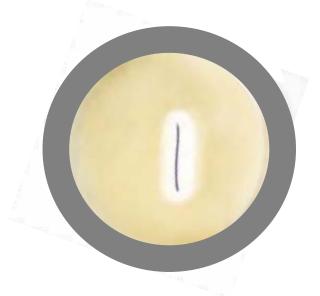
Resistencies:

- Fabl (ENR) gene mutations (E.coli)
- Fabl gene overexpression
- alternative Fabl-genes: FabK (Bacillus spec.)
- innate resistency (P. aeruginosa: multi-drug efflux pumps)

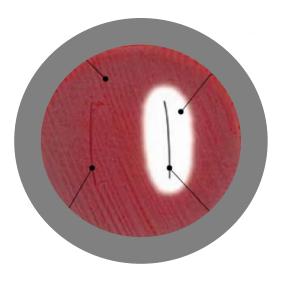
used in soaps, deodorants, toothpaste, shaving creams, toys, socks, trash bags

Triclosan coated sutures

in-vitro effects



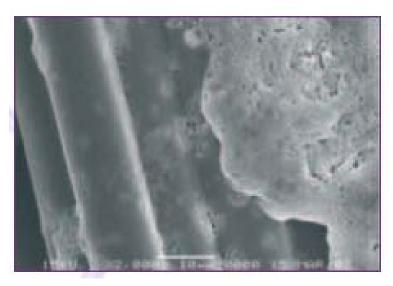
Vicryl Plus[®]
Staph. aureus



Monocryl Plus[®]
E. coli

Triclosan coated Vicryl plus® (Polyglactin 910)





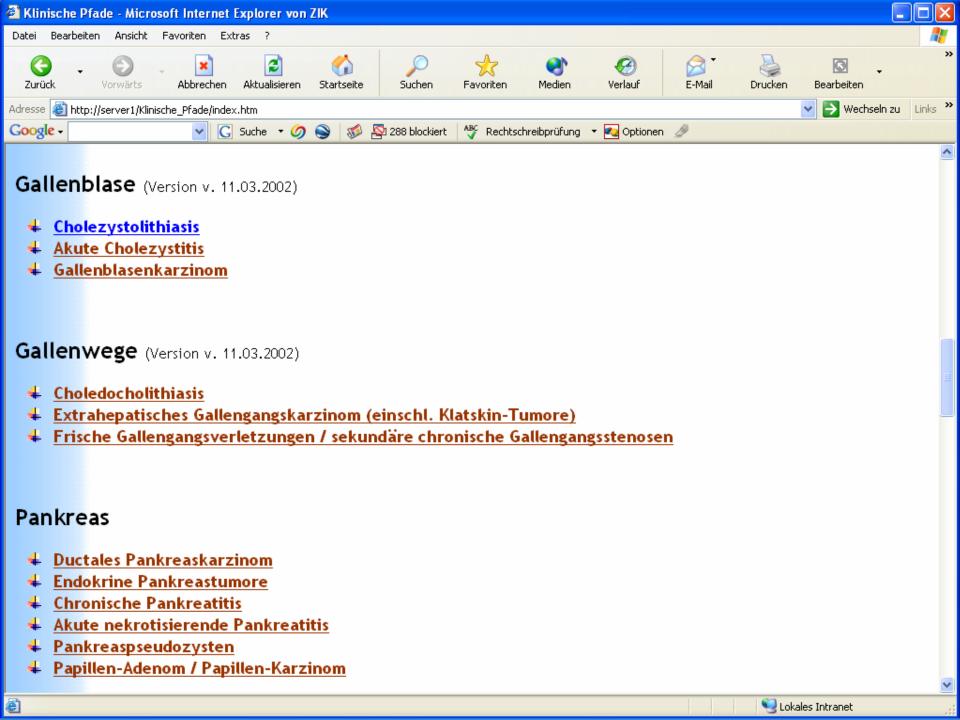
normal suture after 24h

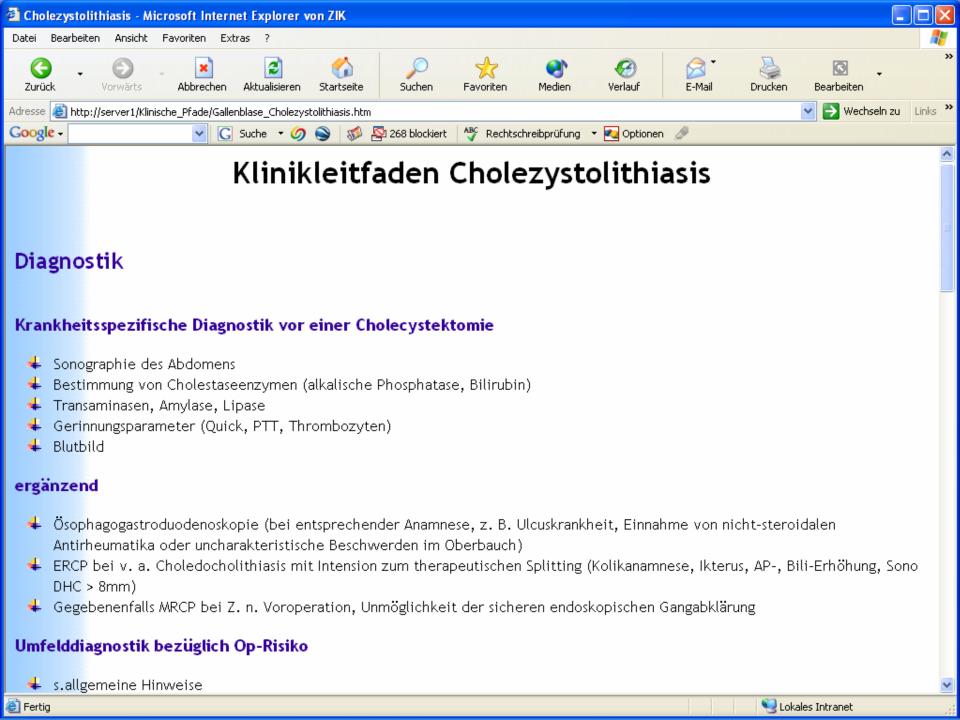
Vicryl plus® after 24h

data aquisation:

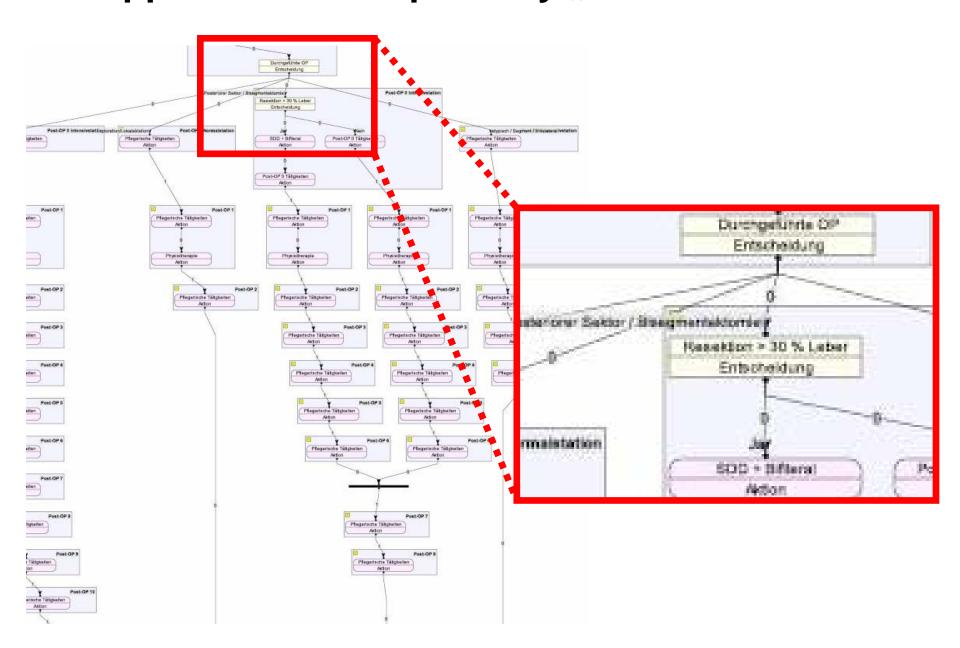
IT-supported clinical pathways (i.s.h. med/SAP)

- standardized treatment of patients
- EBM and guideline based
- simplifies therapy and care process
- guideline for younger doctors

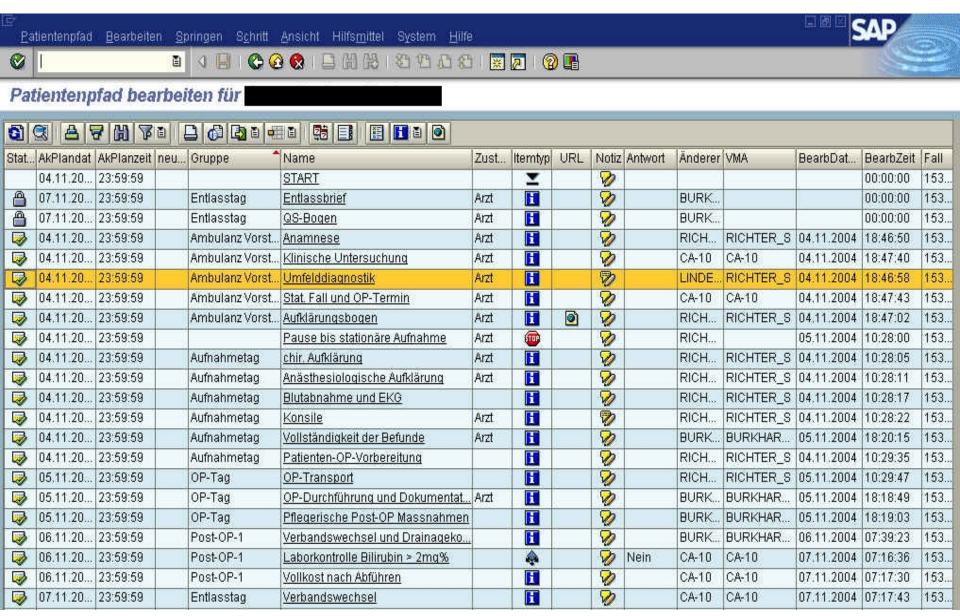


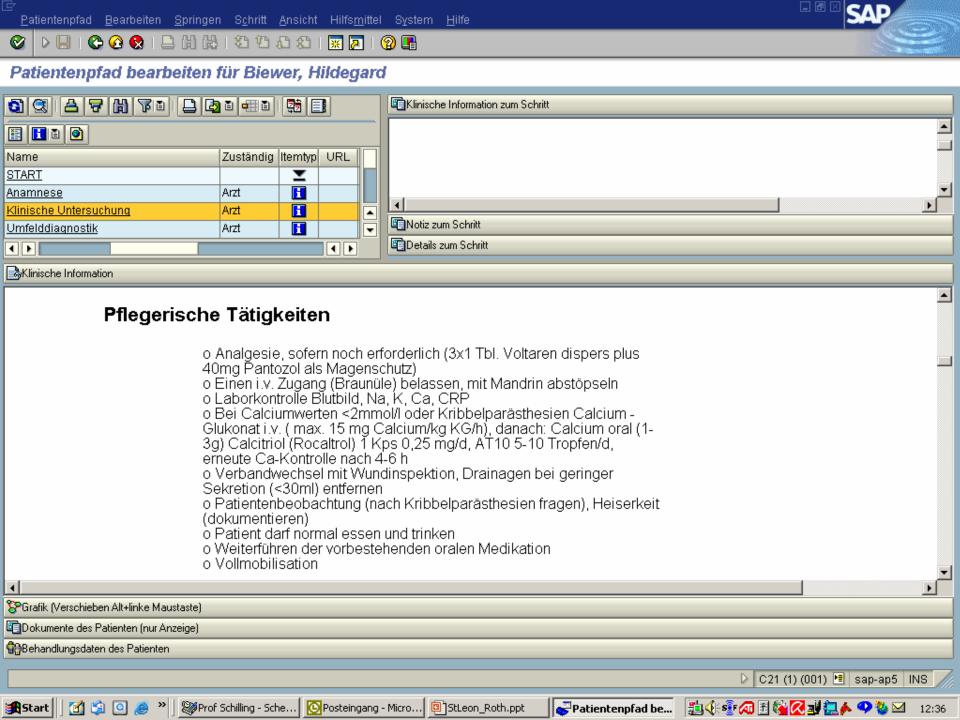


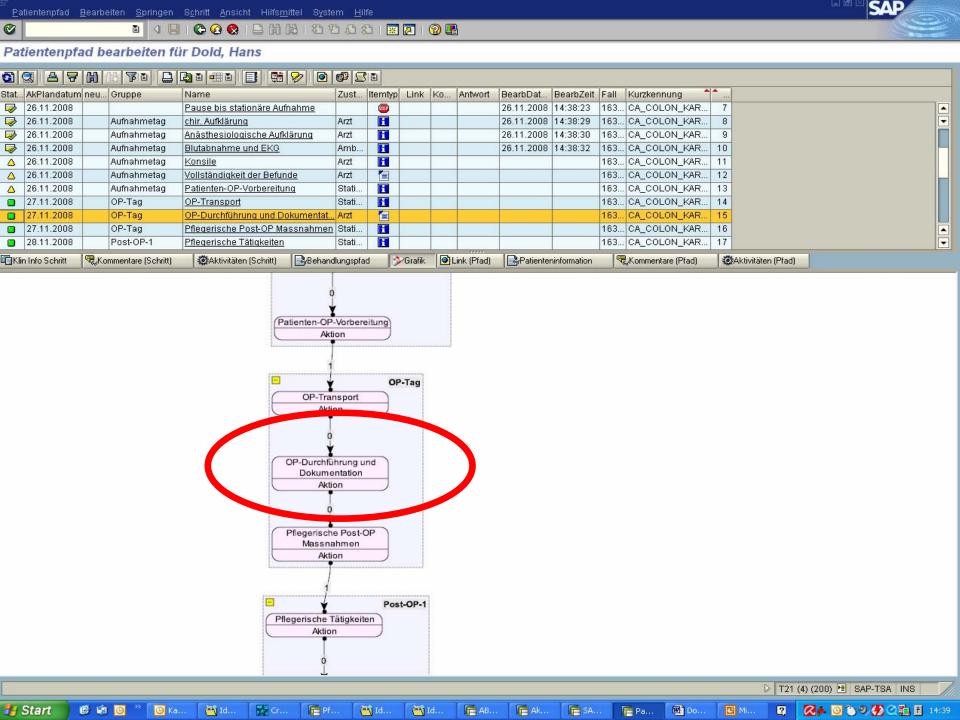
IT-supported clinical pathway "liver resection"

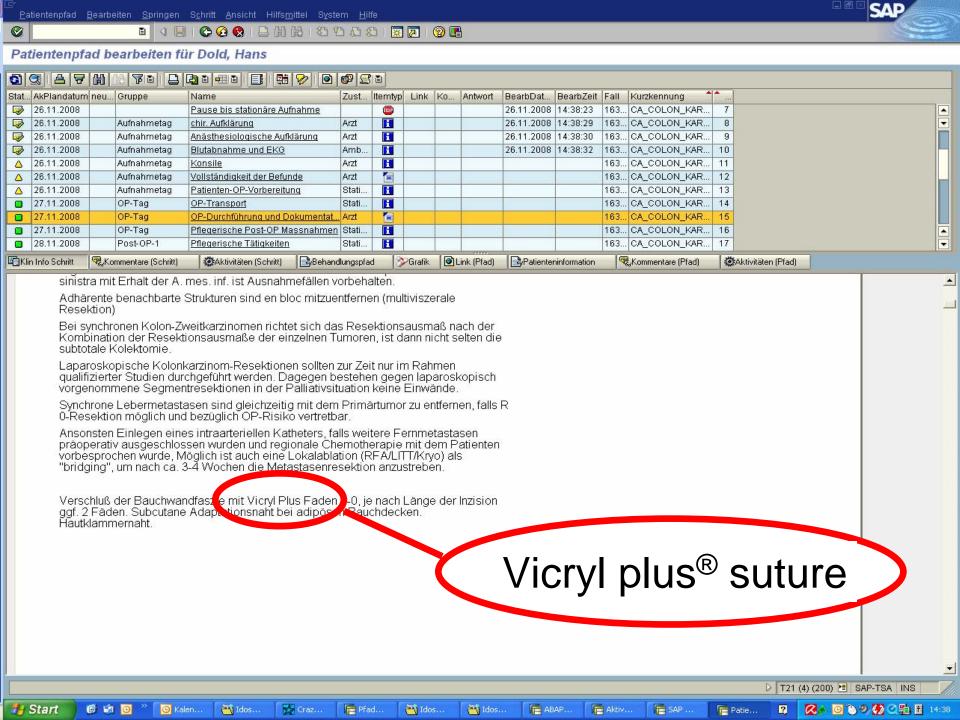


clinical pathway: steps (to-do-list)









parameters	PDS II	Vicryl plus	Р
	n=1045	n=1043	
Gender			0.964
Male	625 (59.8%)	622 (59.6%)	
Female	420 (40.2%)	421 (40.4%)	
Age [years]	60.5 ± 15.9	61.5 ± 14.3	0.744
0-29	3,3	3,7	
30-39	4,9	4,6	
40-49	12,7	12,1	
50-59	21,3	20,8	
60-69	26,7	26,1	
70-79	24,9	25,8	
80-89	6,4	6,2	
>89	0,5	0,5	

parameters	PDS II	Vicryl plus
	n=1045	n=1043
Surgical procedure		
Visceral surgery		
Foregut-Surgery	16	14
Hepatopancreatobiliary- Surgery	14	17
Small bowl	17	14
Colorectal Surgery	35	34
Multi-visceral resection	1,1	1,3
Splenectomy	1,3	1,7
Adrenalectomy	0,8	1,3
Appendectomy	3,2	4
Explorative Laparotomy	2,4	3,2
Tumor resection (GIST, sarcoma)	0,4	0,8
Abdominal lavage	0,7	0,8
Vascular Surgery		
Abdominal Aorta	7,2	7,7
Abdominal Veins	0,2	0,2
Intestinal Arteries	0,4	0,5
Total	100	100

parameters	PDS II	Vicryl plus	Р
	n=1045	n=1043	
BMI			0.217
<18	66 (6.3%)	53 (5.1%)	
18-25	504 (48.2%)	517 (49.5%)	
26-30	333 (31.8%)	335 (32.0%)	
>30	140 (13.4%)	138 (13.2%)	
ASA			0.691
1	41 (3.9%)	49 (4.7%)	
2	394 (37.7%)	401 (38.4%)	
3	442 (42.3 %)	428 (41.0%)	
4	165 (15.8%)	165 (15.8%)	

parameters	PDS II	Vicryl plus	Р
	n=1045	n=1043	
Diabetes mellitus			0.588
Oral antidiabetics	80 (7.7%)	84 (8.1%)	
Insulin	39 (3.7%)	43 (4.1%)	
Immunsuppression	37 (3.5%)	50 (4.8%)	0.156
Steroids	33 (3.2%)	46 (4.4%)	
Azathioprin	4 (0.4%)	3 (0.3%)	
MMF and Steroids	0	1 (0.1%)	
Crohn Disease	39 (3.7%)	46 (4.4%)	0.441
Malignant Disease	453 (43.3%)	419 (40.2%)	0.156
Peritonitis	150 (14.3%)	159 (15.2%)	0.579
Wound status			0.601
Clean	416 (39.8%)	431 (41.1%)	
Clean contaminated	293 (28%)	305 (29.3%)	
Contaminated	246 (23.5%)	224 (21.5%)	
Dirty	90 (8.6%)	82 (7.9%)	
Emergency procedure	370 (35.4%)	366 (35.1%)	0.927

Paramenter	PDS II	Vicryl plus	Р
Total	n=1045	n=1043	
Antibiotics (%)			0.337
Ceftriaxone and Metronidazole	24	27	
Sulbactam and Ampicillin	53	50	
Ciprofloxacin	9	8	
Ceftriaxone	9	9	
Other *	6	6	

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ICU [days]	4.2 ± 9.5 (0- 65)	4.7± 10 (0-71)	0.484
IHOS [days]	8.3 ± 7.5 (5-65)	7.9 ± 8 (3-77)	0.420
OR-Time [min]	153 ± 92.5	161 ± 87	0.380
Wound infections	113 (10.8%)	51 (4.9%)	< 0.001
Mortality	3,4	3,7	0.658

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 Triclosan coating of sutures reduces wound infection in abdominal surgery

 IT-supported clinical pathways facilitate the study of large populations with low costs